FDA Executive Summary

Prepared for the
Spring 2025 Review by the
FDA's Pediatric Advisory Committee

REFLECT™ Scoliosis Correction System (H210002)

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I. INTRODUCTION

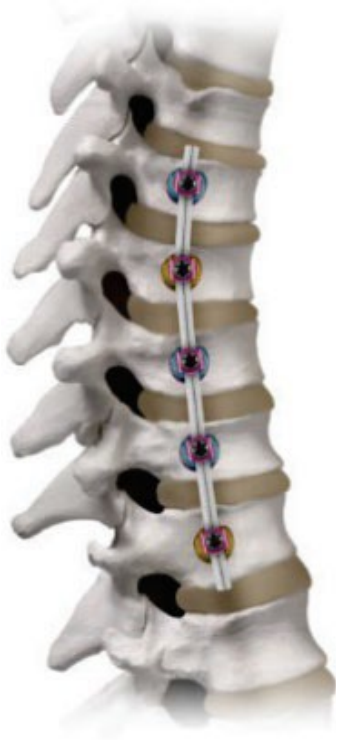
In accordance with the Pediatric Medical Device Safety and Improvement Act, this review provides a safety update based on the post-market experience with the use of the REFLECT™ Scoliosis Correction System ("REFLECT™") in pediatric patients since approval in 2023. The purpose of this review is to provide the Pediatric Advisory Committee (PAC) with post-market safety data so the committee can advise the Food and Drug Administration (FDA) on whether they have any new safety concerns and whether they believe that the Humanitarian Device Exemption (HDE) remains appropriate for pediatric use. This document summarizes the safety data the FDA reviewed since HDE approval in May 2023. It includes data from the sponsor's Annual Report, post-market medical device reporting (MDR) of adverse events (AEs), and peer-reviewed literature.

II. INDICATIONS FOR USE

The REFLECT™ Scoliosis Correction System is indicated for skeletally immature patients who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, who have a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear.

Modifications from the Humanitarian Use Device (HUD) Designation:
The Indication for Use statement was modified from that granted for the HUD designation. The HUD designation was, "for treatment of skeletally immature patients (Risser >5) with a major Cobb angle ≥30°, who require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, and who have failed bracing and/or are intolerant to bracing." It was modified for the HDE approval as follows: removed Risser sign as a Risser score less than 5 is synonymous with skeletally immature patients; and, identified Cobb angle range to better reflect the study population. The resulting Indications for Use statement falls within the HUD designation.

III. BRIEF DEVICE DESCRIPTION



The REFLECT™ Scoliosis Correction System is a non-fusion spinal device intended for treatment of idiopathic scoliosis. It is designed for continued growth and mobility and deformity correction, and accomplishes this by holding spinal segments in a natural, anatomic position using non-rigid materials. The system consists of a polymeric cord used in conjunction with monoaxial screws, locking caps, and staples. The size and number of screws are dependent on the desired correction as well as the length and position of the cord. The cord is placed into the screw head and secured with a locking cap. Single or dual staples may be used for additional fixation of screws to the vertebral bodies and are intended for anterior use only. Manual surgical instruments are used to tension the implant assembly to provide corrective forces. The REFLECT™ Scoliosis Correction System consist of polyethylene terephthalate (PET) cords, monoaxial screws, locking caps, and staples. The PET cord has an attached collet made from titanium alloy, which is removed following tensioning. REFLECT™ screws are composed of titanium alloy, and are available with or without hydroxyapatite (HA) coating. Locking caps and staples are made from titanium alloy. The screws are implanted on the convex side of the curve, with staples for additional fixation, and the cord is inserted into each screw head. After the cord is tensioned, locking caps secure the entire construct.

The REFLECT™ Scoliosis Correction System employs a growth modulation technique in which the growth of the patient is used to achieve scoliosis correction. Compression is applied to the convex side of the spine by tensioning the cord. Single or dual cords may be used for each curve per the preference of the surgeon to meet the surgical goals of each patient.

Device Type	Image	Sizes	Material
Cord		Diameters: 4.0, 5.0mm Lengths: 125, 250, 350mm	Cord: PET Collet: Titanium Alloy TAV (ASTM F136)
Monoaxial Screw		Lengths: 20-100mm (2.5mm increments) 100-120mm (10mm increments) Diameters: 4.0-6.5mm (0.5mm increments) 6.5-10.5mm (1mm increments)	Titanium Alloy TAV (ASTM F136) HA Coating – optional (ASTM F1185)

Locking Cap		One Size	Titanium Alloy TAV (ASTM F136)
Staples		Single: 4.0-7.5mm Dual: Small, Medium, Large, Extra Large	Titanium Alloy TAV (ASTM F136)

IV. REGULATORY HISTORY AND CURRENT STATUS

The REFLECT™ Scoliosis Correction System received Humanitarian Use Device designation (HUD DEV-2019-0433) on February 6, 2020. The HDE was approved on May 15, 2023 by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (H210002). A summary of the HDE and PAS Annual Reports submitted for The Tether™ are presented in Table 1.

Table 1. H210002 Regulatory History

File	Content	Status
H210002/RX	PAS 6-month Report	Report OK
H210002/RX	HDE 1-year Annual Report	Report OK
H210002/RX	PAS 1-year Annual Report	Report OK

V. SUMMARY OF CLINICAL DATA USED TO SUPPORT HDE APPROVAL

Globus Medical collected the clinical data used to support this HDE submission per an institutional agreement, as part of prospectively enrolling FDA-Approved Investigator-initiated Investigational Device Exemption (IDE) clinical study (G170023) for all subjects (N=20), who were enrolled and treated with Globus Medical implants for scoliosis correction. The study was approved by the site's Institutional Review Board (IRB). The majority of the subjects were female (16/20, 80%), and the mean age at time of surgery was 12.3 years. All study subjects were previously surgically treated using components of CREO® and TRANSITION® implants that are FDA-cleared for spinal fusion (K124058, K073439, respectively), and are nearly identical to components of the REFLECT™ Scoliosis Correction System; the REFLECT™ screws have a more rounded edge at the screw head opening compared to the CREO® screws and the REFLECT™ locking caps were modified to accommodate this change. Study subjects were prospectively evaluated for clinical and radiographic outcomes. A primary probable benefit assessment collected for all subjects was curve magnitude as determined by Cobb angle. Radiographic images were qualitatively analyzed using independent radiologists for assessment of device loosening, device migration, and device breakage; and using an independent radiologist for quantitative assessment of scoliosis measures including Cobb angles. Adverse Events (AEs) were reported and assessed by the investigator and an independent Clinical Events Committee (CEC).

The primary probable benefit endpoint of this single-arm study was based on Cobb angle measurement of the subject's major coronal curve at Month 24. Individual subject success was defined as a major curve less than or equal to 40 degrees at Month 24. For Cobb angle measurements, the superior and inferior end vertebrae of the curve were determined pre-operatively and held constant across all timepoints for direct comparison.

Individual subject success was defined as achievement of a Cobb angle less than or equal to 40 degrees at Month 24. Fifteen (15) out of 17 subjects with Month 24 data (88.2%) met the success criteria in this study. Success rates at 12 months following treatment (Month 12) were also assessed. At Month 12, the mean major Cobb angle improved 21.9% from 48.0 degrees to 26.1 degrees. At Month 24, the mean major Cobb angle improved 21.2% from 48.0 degrees to 26.8 degrees.

The risks of this device are based on data collected in a clinical study conducted to support HDE approval. In this clinical study there were 148 AEs reported in all 20 subjects (100%). Six (6) AEs in N=6 subjects were classified as either serious (SAE) or device-related, with the most common event type reported as suspected cord break (N=4). Other event types included progression of instrumented curve (N=1) and overcorrection of instrumented curve (N=1). All SAEs in these 6 subjects (6/20, 30%) resulted in secondary surgery. One subject (1/20, 5%) with curve progression and four subjects (4/20, 20%) with suspected cord breakages had a subsequent surgery to convert to posterior spinal fusion, and one subject (1/20, 5%) with overcorrection of their curve underwent partial implant removal/revision without posterior fusion. SAEs represented 4.1% of total AEs.

The partial removal/revision rate reported for subjects in the study was 5% (1 event in 1 subject), and the reoperation rate was 25% (5 events in 5 subjects), resulting in an overall 30% rate of subsequent surgery. There were no deaths or serious neurologic AEs.

REFLECT™ is intended to use the patient's inherent remaining growth to correct and stabilize the spinal deformity without fusion. The device provides a non-fusion treatment with the potential to avoid the adverse consequences associated with fusion which include decreased spinal motion, pseudarthrosis, adjacent spinal segment degeneration, neurological complications, pain, implant failure/breakage, and subsequent or repeated surgical intervention.

Patient perspectives were also considered in determining probable benefits and risks for the device. Patient perspectives considered for the REFLECT™ Scoliosis Correction System included results from the SRS-30 outcome questionnaire, which was collected in the clinical study as a secondary endpoint. These patient-reported outcomes were considered as part of the benefit-risk assessment for the subject device, and as noted above, were generally positive in terms of patient self-image and patient satisfaction with treatment.

In conclusion, given the available information above, the data on the REFLECT™ Scoliosis Correction System collected under the study support treatment of progressive idiopathic scoliosis, and the probable benefits outweigh the risks.

VI. POST-MARKET DATA: ANNUAL DISTRIBUTION NUMBER

Section 520(m)(6)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows HDEs indicated for pediatric use to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). On December 13, 2016, the 21st Century Cures Act (Pub. L. No. 114-255) updated the definition of ADN to be the

number of devices "reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States." Based on this definition, FDA calculates the ADN to be 8,000 multiplied by the number of devices reasonably necessary to treat an individual. Based on OUS data supporting the implantation of two cords on the same curve (dual cord) or two scoliotic curves of the spine (double curve) across multiple spinal levels, the ADN for the REFLECT™ Scoliosis Correction System was determined to be 8,988 cords, 84,216 screw/locking cap assemblies, 64,728 single staples, and 9,744 dual staples.

The first HDE Annual Report was submitted on May 14, 2024 which included the reporting period from May 15, 2023 through April 30, 2024. Table 2 provides the number of device components distributed in the first year (May 2023-April 2024) in the United States. To date, there have been 16 tether cases utilizing the HDE approved REFLECT™ on the U.S. market.

Table 2. Annual Distribution Number - Reporting Period: May 2023-April 2024

Device Type	Annual Distribution Limit	Total sold (5/15/23 - 4/30/24)
Cords	8,988	33
Screws	84,216	161
Locking Caps	84,216	214
Single Staples	64,728	23
Dual Staples	9,744	19

VII. POST-MARKET DATA: POST-APPROVAL STUDY (PAS)

PAS Conditions of Approval

The REFLECT™ Scoliosis Correction System HDE (H210002) was approved on May 15, 2023.

The objective of the PAS study is to assess the ongoing safety and probable benefit of the REFLECT™ Scoliosis Correction System in a registry population.

The PAS is a prospective, multi-center, single-arm, post-approval US registry study to provide ongoing safety and probable benefit assessment of the REFLECT™ Scoliosis Correction System in treatment of skeletally immature patients with idiopathic scoliosis. Skeletal maturity will be assessed using both the Risser grade and Sanders score. Once enrolled, the patients will be followed through 60-months from the time of each patient's index surgery, with interim visits at immediate post-operative up to 6-weeks, 6-months, 12-months, 24-months, and 60-months post-procedure. One hundred (100) patients will be enrolled in this study. This study will include a minimum of 5 US centers, with a maximum of 20 patients at any one site, with sequential enrollment from each site that agrees to participate.

The primary safety endpoints are serious adverse events (SAEs), and device- or procedure-related AEs. Additional safety analyses will include the rate of AEs, including by relatedness to device or procedure and severity, time-to-event, including means and ranges if applicable, and rate of reoperation, including by type of reoperation.

The primary probable benefit endpoint is maintenance of major Cobb angle less than or equal to 40 degrees at 60-months post-surgery.

Secondary probable benefit endpoints will be analyzed up to 60-months post-surgery, and will include the following:

1. Curve progression no greater than 10 degrees of any secondary curve above or below the implant, or development of a new curve equal to or greater than 40 degrees.
2. Device integrity failures including cord breakage and screw migration.
3. Composite endpoint analysis (maintenance of major Cobb angle less than or equal to 40 degrees AND freedom from SAEs during the REFLECT™ Scoliosis Correction System procedure and procedure/device related SAEs following surgery).
4. Analysis of the failure attributable to conversion to another spinal implant OR major Cobb angle that exceeded 40 degrees at defined follow-up visit OR any progression of the major curve at defined follow-up compared to baseline OR death OR permanent disability.
5. Mean score of Scoliosis Research Society 22r (SRS-22r) patient questionnaire.

These safety and probable benefit data will be collected from each patient at pre-operative, immediate post-operative up to 6-weeks, 6-months, 12-months, 24-months, and 60-months post-operatively.

Descriptive statistics and 95% confidence intervals will be presented for all analyses. For continuous variables, means and standard deviations will be shown. For categorical variables, frequencies and percentages will be presented.

From the date of study protocol approval, you must meet the following timelines for the REFLECT™ Scoliosis Correction System Registry as follows:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 24 months
- 100% of subjects enrolled within 36 months

PAS Study Status

The PAS protocol was approved on July 13, 2023 (H210002/S001). The 12-month report was received on July 24, 2024. As of this date, one (1) clinical site has been selected for patient enrollment and has received Institutional Review Board (IRB) approval. The site initiation/training visit was scheduled for August 9, 2024. Patient enrollment is to begin as soon as the site initiation has been completed. As of the 12-month PAS report, the study progress is delayed, however mitigations were determined not to be needed at that time. Per the HDE Approval Letter, this PAS study is estimated to be completed by May 31, 2032.

VIII. ADVERSE EVENTS

Known Adverse Events

AEs collected during the clinical study that were used to support the safety and probable benefit of the REFLECT™ Scoliosis Correction System in subjects with pediatric idiopathic scoliosis were presented in the SSPB at the time of HDE approval. One hundred and forty-eight (148) AEs were identified in all 20 subjects in the study population. Table 7 lists all AE types reported in the clinical study that were classified as related to the device or procedure. A total of 106 device- or procedure-related AEs were identified. The most common device or procedure-related AEs by subject occurrence include Respiratory – Diminished Bases/Sounds/Capacity (15/20, 75%), Gastrointestinal (12/20, 60%), and Pain – Thorax (11/20, 55%).

Table 3. Known AE Types Related to the REFLECT™ Device or Procedure

AEs Related to Device or Procedure
1. Cardiovascular
2. Dysesthesia – Thorax
3. Gastrointestinal
4. Muscle spasms
5. Musculoskeletal
6. Other
7. Pain – Back
8. Pain – Other
9. Pain – Thorax
10. Pain – Upper extremities
11. Paresthesia – Other
12. Radiographic – Suspected Screw/Staple Finding
13. Radiographic – Suspected Cord Finding
14. Respiratory – Atelectasis
15. Respiratory – Congestion/Cough
16. Respiratory – Diminished Bases/Sounds/Capacity
17. Respiratory – Pleural Effusion/Edema
18. Respiratory – Pneumothorax
19. Respiratory – Other
20. Surgery – Index Levels
21. Wound Issue

From the AEs reported in Table 7, Table 8 summarizes the three (3) AE types classified as device- or procedure-related SAEs. Six (6) total SAEs were reported for this study. Suspected cord break was the most common SAE type, and accounted for 4 of the 6 total SAEs, followed by one (1) instance of curve progression and one (1) instance of overcorrection. The subjects with suspected cord breakage (4) and curve progression (1) underwent reoperation to posterior spinal fusion, and the subject with overcorrection had some implants removed without spinal fusion. Two (2) of the reoperations occurred after 30 months. The revision rate was 5%, and the reoperation rate was 25%, for an overall 30% rate of subsequent surgery. Fusion was avoided in

17 of the 20 subjects (85%) through Month 24, and in 15 of the 20 subjects (75%) post-operatively following treatment (Month 37).

Table 4. Known SAE Types Related to the REFLECT™ Device or Procedure

SAEs Related to Device or Procedure
1. Progression of instrumented curve 2. Overcorrection of instrumented curve 3. Suspected cord break

Literature Review

The sponsor performed a clinical literature search in their HDE Annual Report of published data on the clinical use of REFLECT™ and no published reports were identified. However, given that REFLECT™ is a second-of-a-kind device, literature reported in the most recent annual report for the first-of-a-kind tether from August 2023 to August 2024 (H190005/RX) is included for completeness. This is because the literature lacks information specifying either tether device. Scoliosis, tether, tethering, spine, anterior vertebral body tethering, vertebral body tethering, and investigators' last names who previously published on AVBT including Samdani, Larson, Miyanji, Diab, Hoernschemeyer, Betz, Cuddihy, and Antonacci, were used as search terms and the following inclusion/exclusion criteria were used to further refine the articles to criteria relevant for the HDE.

Inclusion Criteria:

- It provides relevant information regarding technical and clinical features of the device subject to the search, or
- It provides relevant information regarding performance and/or safety of the device subject to the search, or
- It provides information relevant to determining the probable benefit of the subject device, and
- It contains sufficient information for a rational and objective assessment, and
- It is based on an appropriate study design

Exclusion Criteria:

- Those involving implants other than those of interest
- Isolated case reports
- Random experience
- Reports lacking sufficient detail to permit scientific evaluation
- Unsubstantiated opinions
- Non-clinical studies
- Foreign language (non-English) literature

After removing duplicates, and reading the titles, abstracts, and full-texts, 21 articles were determined to be relevant based on the H190005 sponsor's inclusion and exclusion criteria[1-21].

An additional clinical literature search in PubMed was performed by FDA for articles published from December 2023 to December 2024. The following search terms were used: scoliosis, tether.

After reading the titles, abstracts, and full-texts, and excluding non-clinical studies, review papers, tethered spinal cord studies, non-AVBT studies, and studies that did not report any adverse events, three (3) articles were found.[22-24] For the purposes of this executive summary, only articles that contain adverse event information are included. A total of 24 articles are discussed below.[1-24]

Out of the 24 total articles, 16 were from US sites, four were from outside the United States (OUS) sites, and four included both US and OUS sites. It is important to note that the literature articles do not indicate the specific device type used. However, all literature articles did study AVBT devices and therefore were included in this analysis. A total of 1,745 patients were reported on across these 24 articles with 761 adverse events:

- Spinal curvature overcorrection
    - 3.3% (n = 58) compared to 5% from clinical data results in the SSPB
- Curve progression
    - 1.7% (n = 29) compared to 5% from clinical data results in the SSPB
- Broken tethers
    - 20% (n = 349) compared to 20% from clinical data results in the SSPB
- Other mechanical complications (screw loosening/pullout/migration/misplacement, tether loosening)
    - 0.8% (n = 14) compared to 5% from clinical data results in the SSPB
- Revision surgery
    - 8.9% (n = 155) compared to 5% from clinical data results in the SSPB
- Convert to fusion
    - 2.1% (n = 36) compared to 25% from clinical data results in the SSPB
- Pulmonary/thoracic complications (pneumothorax, pleural effusion/edema, chylothorax, atelectasis, congestion/cough, diminished bases/sounds/capacity)
    - 0.9% (n = 16) compared to 20-75% from clinical data results in the SSPB
- Radicular extremity pain (paresthesia)
    - 0.2% (n = 3) compared to 10% from clinical data results in the SSPB
- Infection
    - 0.2% (n = 3) compared to 15% from clinical data results in the SSPB
- Cerebral spinal fluid (CSF) leak
    - 0.2% (n = 3) compared to 0 from clinical data results in the SSPB
- Ureteral Injury
    - 0.1% (n = 1) compared to 0 from clinical data result in the SSPB

Summary of Literature

The studies found in this literature review suggest probable benefits of AVBT systems such as REFLECT™ with respect to the treatment of skeletally immature patients with idiopathic scoliosis. From the clinical data documented in the SSPB used to support safety and probable benefit for REFLECT™ a total of 148 adverse events were observed in all 20 total subjects. All event types from the literature search were identified at time of HDE approval as potential adverse effects (e.g., adverse events) as documented in the SSPB except for CSF leak and ureteral injury. CSF leak is not an unexpected adverse event following any spinal surgical

procedure, given the proximity of screws to the dural sac, and is a known adverse event observed in previous literature reviews associated with the first-of-a-kind approved tether device (H190005). Ureteral injury is not an unexpected adverse event following surgery particularly near the lower thoracic and lumbar regions of the spine. Subsequent surgery rates are slightly higher than those reported in the SSPB, but are comparable and within the ranges reported in the SSPB for the previously-approved, first-of-a-kind tether device (H190005). One limitation to the adverse events published in the literature is there may be redundancy in the adverse event reporting. As researchers increase their publications on spinal tether patients, they may be reusing the same patient data, or a subset of patient data, in different articles to present different findings. Therefore, it is not possible to know if an adverse event has already been reported in the literature without patient level data. Given this potential for redundancy, we believe that the 761 adverse events for the 1,745 patients published in these 24 articles may be an overrepresentation of the adverse events. These 761 adverse events are likely a conservative overestimation for these 1,745 patients. If any redundancies were able to be removed, it would only help to improve the safety profile of this device type.

While the list of adverse events is much more comprehensive in the SSPB as compared to the literature, this search demonstrates that the types of adverse events documented in the literature are expected given the clinical data published in the SSPB for the REFLECT™ - Scoliosis Correction System. It does not appear that any additional safety signals nor concerns have arisen since HDE approval.

Overview of MDR Database

Strengths and Limitations of MDR Data

Each year, the FDA receives several hundred thousand MDRs of suspected device-associated deaths, serious injuries and malfunctions. The MDR database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDR reports can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a “real world” setting/environment, including:
    - Rare, serious or unexpected adverse events;
    - Adverse events that occur during long-term device use;
    - Adverse events associated with vulnerable populations;
    - Off-label use; and
    - Use error

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several

important post-market surveillance data sources. Other limitations of MDRs and FDA's internal MDR database include:

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device caused a specific event can be difficult based solely on information provided in each report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MDR data is subjected to reporting bias, attributable to potential causes such as reporting practice, increased media attention, and/or other agency regulatory actions.
- MDR data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.

MDRs Associated with REFLECT™

FDA's internal MDR Database was searched in October 2024 utilizing the following search criteria:

1. Manufacturer Name: Globus
   Brand name, generic name, or concomitant product: "REFLECT"
   - 7 MDRs found
2. Manufacturer Name: Globus
   Narrative text: "reflect", "scoliosis", "correction", "system"
   - No additional MDRs were found that incorporated any combination of the device trade name in the narrative text.
3. PMA/510k number (document search field): H210002
   - No additional MDRs were found that incorporated the applicable HDE number within the document search field.

The search resulted in seven (7) MDRs, all of which occurred OUS from May 15, 2023 to October 1, 2024. Descriptive summaries of the 7 unique MDRs are provided below.

MDR #1: 3004142400-2024-00152
It was reported that a revision surgery was needed to replace a REFLECT implant that failed post-operatively (female patient, age unknown). Explantation occurred 17 months after index surgery. This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. However, mechanical/structural device failure such as cord breakage is a well-documented risk with this device type, as noted in the literature and the SSPB.

MDR #2: 3004142400-2024-00159It was reported that a female patient (age unknown) had complications (i.e. pneumonia) following a REFLECT implant surgery. This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined.

No other information was provided for this MDR. However, pulmonary complications are a known risk associated with tether surgery, as documented in the literature and SSPB.

MDRs #3: 3004142400-2024-00160
Pain secondary to genitofemoral nerve was reported after REFLECT implant surgery, and the patient (female, age unknown) had to undergo traditional fusion surgery to treat the failed implant. This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. Nerve pain and conversion to fusion are both well-documented risks associated with tether surgery, as noted in the literature and the SSPB.

MDRs #4: 3004142400-2024-00161
It was reported that a REFLECT implant cord had broken between the 9th and 10th screws post-operatively (female patient, age unknown). This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. Tether breakage is a known risk associated with the device type.

MDRs #5: 3004142400-2024-00162
It was reported that a REFLECT implant cord had broken between T10 and T11 at 12 months post-operatively (female patient, age unknown). This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. Tether breakage is a known risk associated with the device type.

MDRs #6: 3004142400-2024-00163
It was reported that a REFLECT implant cord had broken between at L2/L3 post-operatively (female patient, age unknown). This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. Tether breakage is a known risk associated with the device type.

MDR #7: 3004142400-2024-00164
It was reported that a revision surgery was needed to replace a REFLECT implant due to worsening of spinal curvature (male patient, age unknown). Explantation occurred 13 months after index surgery. This event occurred in the UK. The device was unavailable for evaluation, and root cause was unable to be determined. No other information was provided for this MDR. Curve progression is a well-documented risk with tether surgery, as noted in the literature and the SSPB.

Summary of MDRs

All 7 MDRs are expected given the nature of tether surgery. Table 9 summarizes all MDRs associated with REFLECT™ since its approval in May 2023.

Table 5. MDRs for REFLECT™

Adverse Event Type	Number of Events	Patient Age (years), Sex (if known)	Relationship to Device
Revision - Replacement	2*	- Unknown age, female - Unknown age, male	Investigation ongoing
Pulmonary/vascular	1	- Unknown age, female	Investigation ongoing
Curve progression	1*	- Unknown age, male	Investigation ongoing
Convert to fusion	1**	- Unknown age, female	Investigation ongoing
Mechanical complication (including broken tether)	3	- Unknown age, female - Unknown age, female - Unknown age, female	Investigation ongoing
Nerve pain	1**	- Unknown age, female	Investigation ongoing

*MDR #3004142400-2024-00164 is counted twice: once for revision (replacement) and once for curve worsening/progression

**MDR #3004142400-2024-00160 is counted twice: once for conversion to fusion and once for nerve pain

IX. SUMMARY

Evaluation of data available to CDRH, including the HDE 1-year Annual Report, MDRs and published scientific literature, has identified no new safety signals compared to what was known and anticipated at the time of HDE approval in May 2023. Based on the available data, and considering the probable benefits and risks, FDA believes that the HDE remains appropriately approved for pediatric use. Therefore, FDA recommends continued surveillance and will report the following to the PAC in 2026:

- Annual distribution number
- Literature review
- MDR review
- Update on the PAS

X. REFERENCES

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