

## **ATTACHMENT 3**

References to glass causing injury  
in devices similar to the RLD

From the MAUDE database at the FDA's website:

**Adverse Event Report  
MEDI-FLEX SEPP 10% POVIDONE IODINE APPLICATOR**

Catalog Number 26-02-86

**Event Description**

When ampule was broken, a sliver of glass penetrated the outer plastic sleeve and cut the employee's hand while blood cultures were being done. There did not appear to be any blood-to-blood contact.

**Brand Name SEPP 10% POVIDONE IODINE APPLICATOR**

**Type of Device APPLICATOR**

**Manufacturer (Section D) MEDI-FLEX  
overland park KS 66210**

Device Event Key 28651

MDR Report Key 27734

Event Key 25929

Report Number 27734

Device Sequence Number 1

Product Code EFQ

Report Source Voluntary

Report Date 11/01/1995

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 11/01/1995

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device EXPIRATION Date 05/01/1998

Device Catalogue Number 26-02-86

Device LOT Number 503032

Was Device Available For Evaluation? Yes

Patient Outcome Other

See

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=27734](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=27734)

From the MAUDE database at the FDA's website:

**Adverse Event Report  
MEDI-FLEX HOSP PRODUCTS IODINE SEPP APPLICATOR**

Catalog Number 260286

**Event Description**

Gauze applicator tip fell off. Pt's skin was prepped with alcohol. Bleeding and small pinhole-like marks noted over intended insertion area. Small piece of glass on skin noted.

**Brand Name IODINE SEPP APPLICATOR**

**Manufacturer (Section D) MEDI-FLEX HOSP PRODUCTS  
overland park KS 66210 2103**

**Device Event Key 11321**

**MDR Report Key 11321**

**Event Key 7379**

**Report Number 11321**

**Device Sequence Number 1**

**Product Code KXF**

**Report Source Voluntary**

**Report Date 09/01/1993**

**1 Device Was Involved in the Event**

**1 Patient Was Involved in the Event**

**Date FDA Received 02/01/1994**

**Is This An Adverse Event Report? No**

**Device Operator Health Professional**

**Device Catalogue Number 260286**

**Device LOT Number 305-002**

**Was Device Available For Evaluation? No Answer Provided**

See [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=11321](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=11321)