

Endoscopy Division

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Smith & Nephew

Dockets Management Branch (HFA-305)
Division of Management Systems & Policy
Office of Human Resources and Management Services
Food and Drug Administration
5603 Fishers Lane
Rockville MD 20852

RE: Docket # 00D-0053

Dear Sir/Madam

I am writing to provide comments on the agency's proposed strategy on the reuse of single use devices, including the two new guidance documents "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals". Smith & Nephew, Inc., Endoscopy Division develops and manufactures orthopedic implants, reusable surgical devices and single use surgical devices for use in general and orthopedic procedures. Most of our single use devices are used during arthroscopic, endoscopic or laparoscopic procedures.

Smith and Nephew Endoscopy Division fully supports the comments submitted by Hyman Phelps and McNamara on behalf of the Association of Disposable Device Manufacturers (ADDM). I do not intend to repeat all of the comments made by the ADDM but rather to provide our perspective on several of the more important aspects of the proposed strategy and to describe the effect of reprocessing on many of our single use devices.

Regulatory Classification and Submissions

Smith & Nephew supports the Agency's commitment to regulate reprocessors and OEMs using the same criteria. To this end, there is currently a classification system in place for the vast majority of devices and thus an alternative risk based system for reprocessed single use products is not necessary. The current classification system is both adequate and applicable.

Reprocessors should be required to make model specific premarket submissions (510(k)s or PMAs) for any product they intend to reprocess. Reprocessing alters the intended use of a single use device, and consequently creates a new device. Furthermore since reprocessing raises new concerns of safety and efficacy, this requirement must include products which may have been exempt from submission as a single use device. These premarket submissions should include all information specified in the April 1996 guidance document on reusable devices, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance and in Labeling- Regulatory Requirements for Medical Devices (FDA 89-423, issued 9/01/1989). Specifically submissions should include the information, testing and validations required to support a claim that a device may be reused (i.e., cleaning, sterilization, and performance, etc.) and how many times, in addition to how the reuse will be tracked.

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Labeling Requirements

By changing a single use device to a reusable device the reprocessor becomes the *de facto* manufacturer of the device and must take responsibility for all aspects of the device design and manufacture. This includes all required labeling and instructions for use as defined in 21 CFR Part 801, plus an indication of the number of uses/reuses that have occurred. Many of the reused devices that we reviewed do not include any Instructions for Use (IFU). The package states "See Original Manufacturers Operating Instructions" (Attachment 1 Photographs of reprocessed product labels). The reprocessor is making an assumption that the hospital still has copies of the OEMs instructions and that the instructions are relevant for reprocessed blades. Reprocessors should not be permitted to abdicate their responsibilities for labeling in this manner. The labels often do not include lot numbers or expiration dates.

We have also seen products labeled as "reprocessed Dyonics" blades which in fact were not our product. Dyonics is a trademark for the Smith and Nephew, Inc., Endoscopy Division. Attachment 5 contains photographs of a device that was labeled as a Dyonics product but in fact is not a Dyonics product.

The reprocessor should be required to remove the original manufacturer's name, identity and/or trademarks from the product – if not the device should be considered mislabeled. It is not enough for the reprocessor to label the package, since during use the package is quickly removed and discarded, and the device appears as an OEM original product, thereby misleading the user and misrepresenting the product.

Furthermore Smith & Nephew strongly opposes the proposal to include warnings, such as risks of reuse, in the original packaging beyond those required by 21 CFR 801. Hyman Phelps and McNamara have clearly and adequately stated the reasons.

Product Specific Issues

Smith & Nephew believes many of our single use products cannot be effectively reprocessed, thereby compromising patient safety and device performance. We have inspected and tested many products reprocessed by third party organizations, and in all cases found the products unfit for use. To illustrate this, I have compiled data for several designs and styles of arthroscopic blades (classified by the Agency as Class I exempt, under 21 CFR 878.1100, Arthroscopic Accessories, Code NBH), using the draft Risk Categorization Scheme issued by the Agency.

Please note that as stated above we believe the current Classification system is both adequate and appropriate – we have chosen to use the risk categorization scheme only for illustrative purposes.

We have provided photographs in Attachments 1 –4 of both new and used devices to demonstrate our concerns with the use of refurbished devices.

I. Risk of Infection

Is the SUD a critical device?

Yes, arthroscopic blades and burrs are considered critical devices because they come into contact with a normally sterile area.

Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed.

We do not have specific complaints of infection as the result of reuse of these products.

We have however, examined blades that had been reprocessed and found that the refurbished/reprocessed blades all had the potential to have sterility concerns for the following reasons: penetration of the packaging materials by the blade, poor seal quality, and the use of sterilization methods which may not been fully validated for use in small lumen devices. (See Attachment 2 for photographs of packaging used for refurbished devices and packaging for new devices) Photographs II-3 and II-4 demonstrate significant particulate matter within the sterile packaging.

Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes our data demonstrates that it is virtually impossible to adequately clean a used arthroscopic blade.

When we inspected reprocessed blades we found that the blades frequently contained contaminants (consistent with adherent tissue and blood) from previous surgical procedures. The design of the blades makes it difficult if not impossible to remove all of the debris from the previous surgery. (See Attachment 4 for photographs of refurbished devices with blood and tissue on the device). Specifically all inner blades have an inaccessible narrow lumen (<5mm) which is the aspiration path for tissue, etc. during surgery. Additionally, curved blades can not be disassembled, and they include a spring section which cannot be cleaned.

End of Flow Chart 1 – High Risk Device

Flow Chart 2 – Inadequate Performance

Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

No, the reusable blades currently on the market are specifically designed from different materials to withstand the rigors of multiple uses.

Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected.

No

Does Postmarket information suggest that using reprocessed SUD may present an increased risk of injury when compared to an SUD that has not been reprocessed.

While there are no specific complaints that could be directly tied to the reprocessing of arthroscopic blades, we have examined many blades and burrs that had been reprocessed and found the following:

1. Dulled cutting surfaces, flattened cutting teeth and edgeform damage

A sharp cutting edge is necessary for optimum performance. The design of these devices make it difficult if not impossible to sharpen the blade without damaging other aspects of the device. Use of a dull blade will rip the tissue as opposed to cutting the tissue. The ripped tissue is more likely to clog the inner lumen of the blade than cut tissue.

Edgeform damage in the form of burrs, metal filings, thinning of base metal of the cutting teeth, modification of angles of the cutting surfaces etc. would likely lead to reduced cutting efficacy, shedding of metal fragments and fracture of metal fragments into the surgical site. (See attachment 3 for photographs of new, unused disposable blades and refurbished blades that would have significant performance issues)

2. Binding/seizing at startup

Damage to hub components from overuse and/or friction from bent blade shafts have been found. These devices have a coating on the inner blade to ensure that it rotates smoothly inside the outer blade. When this coating is damaged it results in poor rotation and binding and seizing of blades upon startup of the blade.

3. Cracking in the plastic hubs

Cracking in the plastic hubs, ranging from microscopic to gross cracking (visible to the naked eye) has been observed in both refurbished and reprocessed blades. In some blades, portions of the plastic components have been missing entirely. This damage would result in hub fractures and loss of blade control during surgery.

Could failure of the device cause death, serious injury or permanent impairment?

No

Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

No.

Can visual inspection determine if performance has been affected?

No.

Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

These devices have a coating on the inner blade to ensure that it rotates smoothly inside the outer blade. When this coating is damaged it results in poor rotation and binding/seizing of blades upon startup of the blade.

Are there recognized consensus standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

No.

End Flow Chart 2 – High Risk

Definitions:

Reprocessing – The proposed definition of reprocessing is not suitable. Initial sterilization of a non-sterile device should be excluded from the text since this activity is the initial process with a new product, and should not be confused with the secondary processing of a used product.

Consensus Standards:

The agency has suggested the development and use of consensus standards to assess the safety and effectiveness of reprocessed single use devices. We are concerned about the practicality of this approach. FDA staff has stated that reprocessing needs to be considered on a model by model basis – this would suggest standards must similarly be considered. Furthermore, based on our experiences we oppose any proposal to permit reprocessors the option to issue Declaration of Conformance to standards, until such time there is sufficient history and evidence of reprocessor performance to ensure device safety and effectiveness.

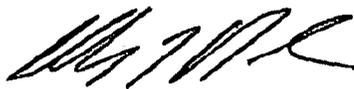
Conclusion

We have demonstrated why the agency should hold reprocessors of single use devices to the same standard as they hold the original manufacturer. Based on our review of reprocessed arthroscopic blades it is clear that these devices pose a significantly higher risk of infection than the product did when it was new.

It also is clear that as the edges of the blades become dull from reuse the blades will be significantly less effective as a cutting tool than when they were new.

I hope the photographs that we have provided are useful to you in reviewing the very dangerous process of reusing devices designed to be single use. Please do not hesitate to contact me at (978) 749-1492 if you have further questions.

Sincerely yours,



Sally L. Maher, Esq.
Director, Regulatory Affairs/Clinical Research
Smith & Nephew, Inc., Endoscopy Division

Attachments

- Attachment 1** **Photographs of Smith and Nephew, Inc., original labels and refurbished product labels**
- Attachment 2** **Photographs of Smith and Nephew Inc. packaged blades and refurbished packaged blades**
- Attachment 3** **Photographs of new blades and refurbished blades**
- Attachment 4** **Photographs of blades which were not adequately cleaned**
- Attachment 5** **Mislabeled refurbished blades**

ATTACHMENT I

Photographs of Smith and Nephew Inc., original labels

And

Refurbished product labels

ATTACHMENT II

Photographs of Smith and Nephew Inc, packaged blades

And

Refurbished packaged blades

ATTACHMENT III

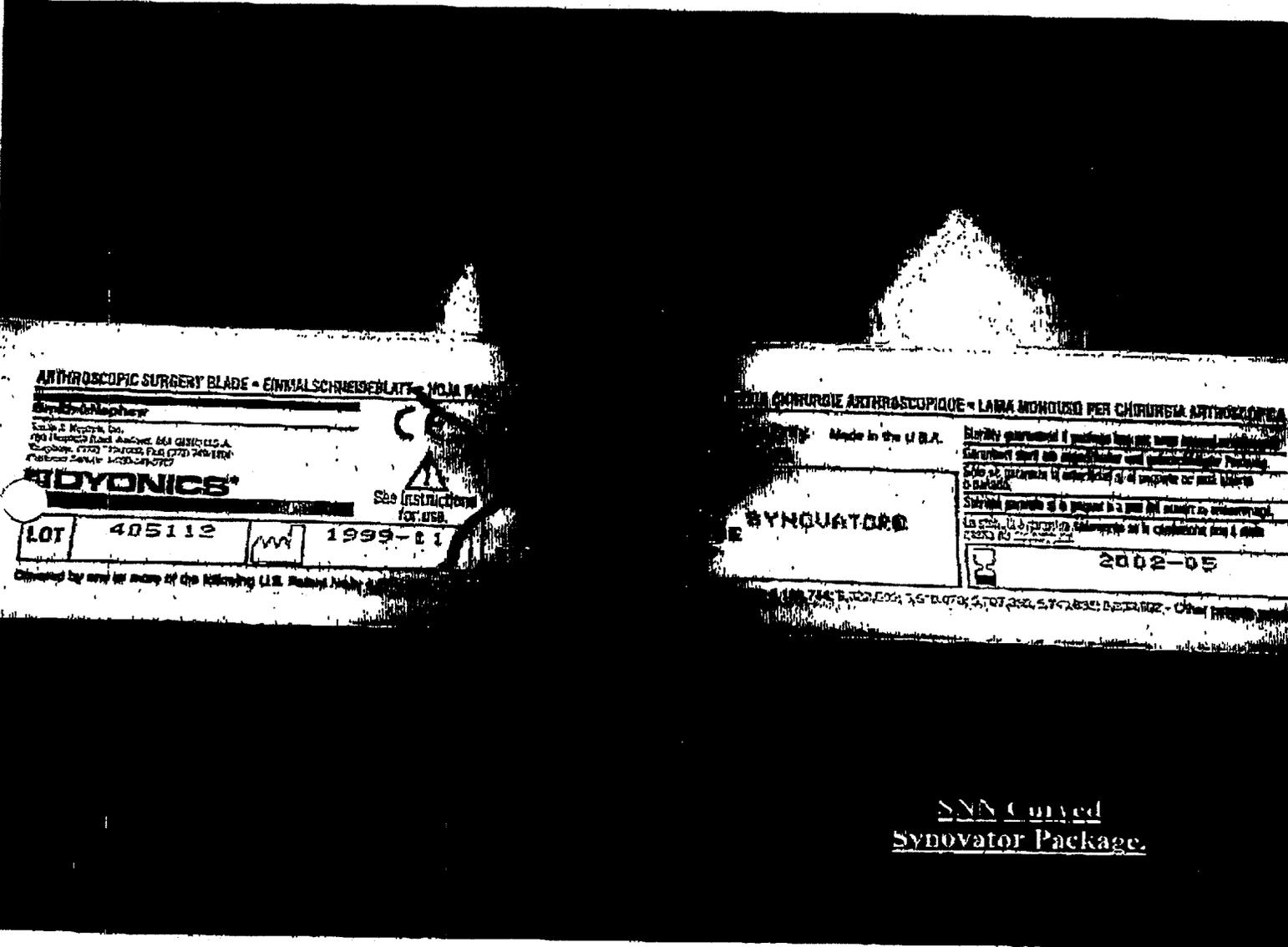
Photographs of new and refurbished blades

ATTACHMENT IV

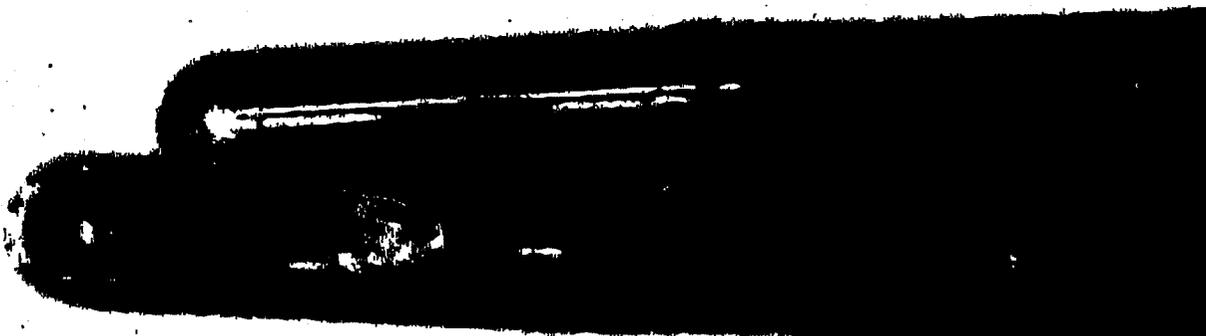
Photographs of refurbished blades, which were not adequately cleaned

ATTACHMENT V

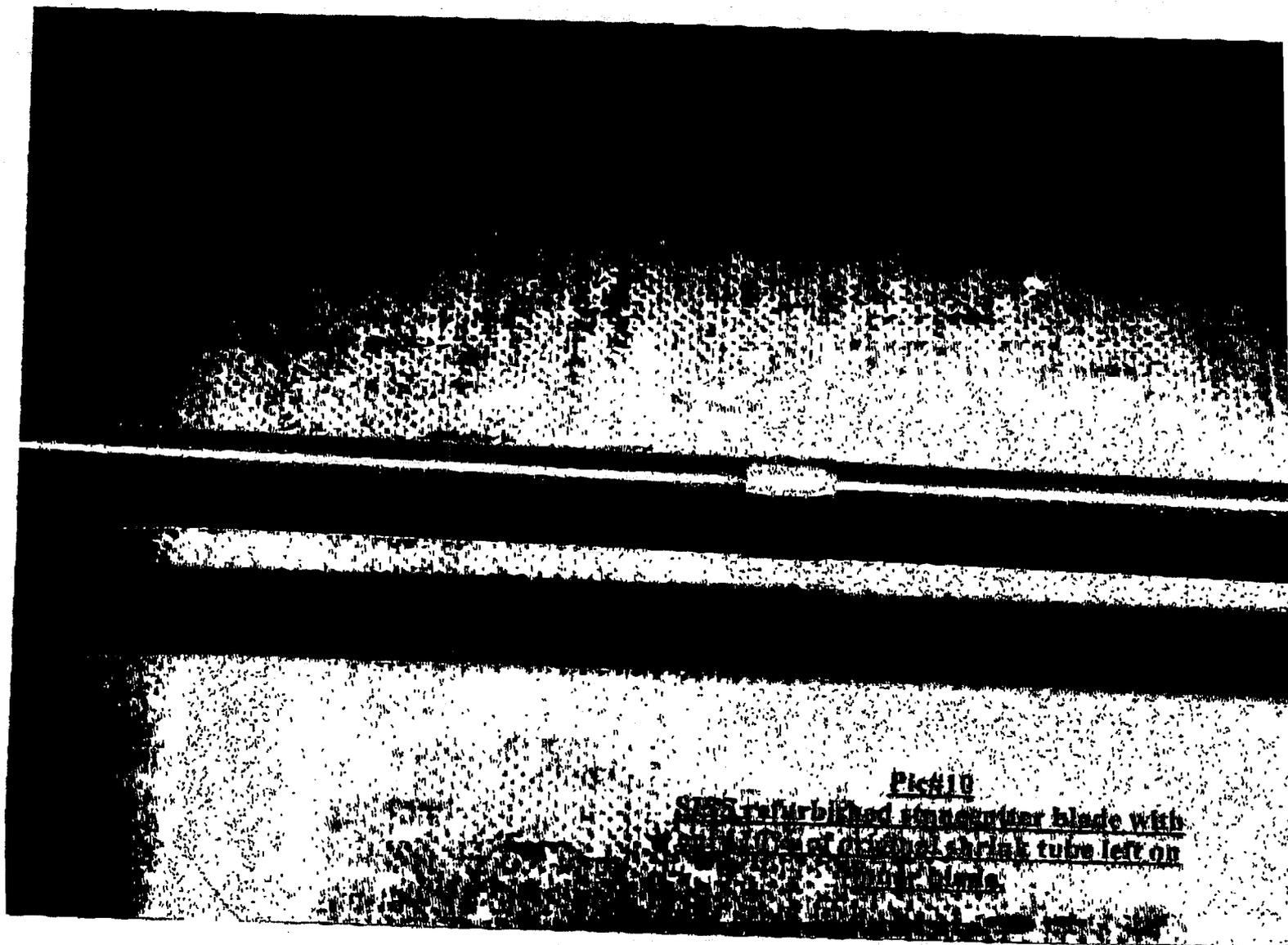
Mislabeled refurbished blade



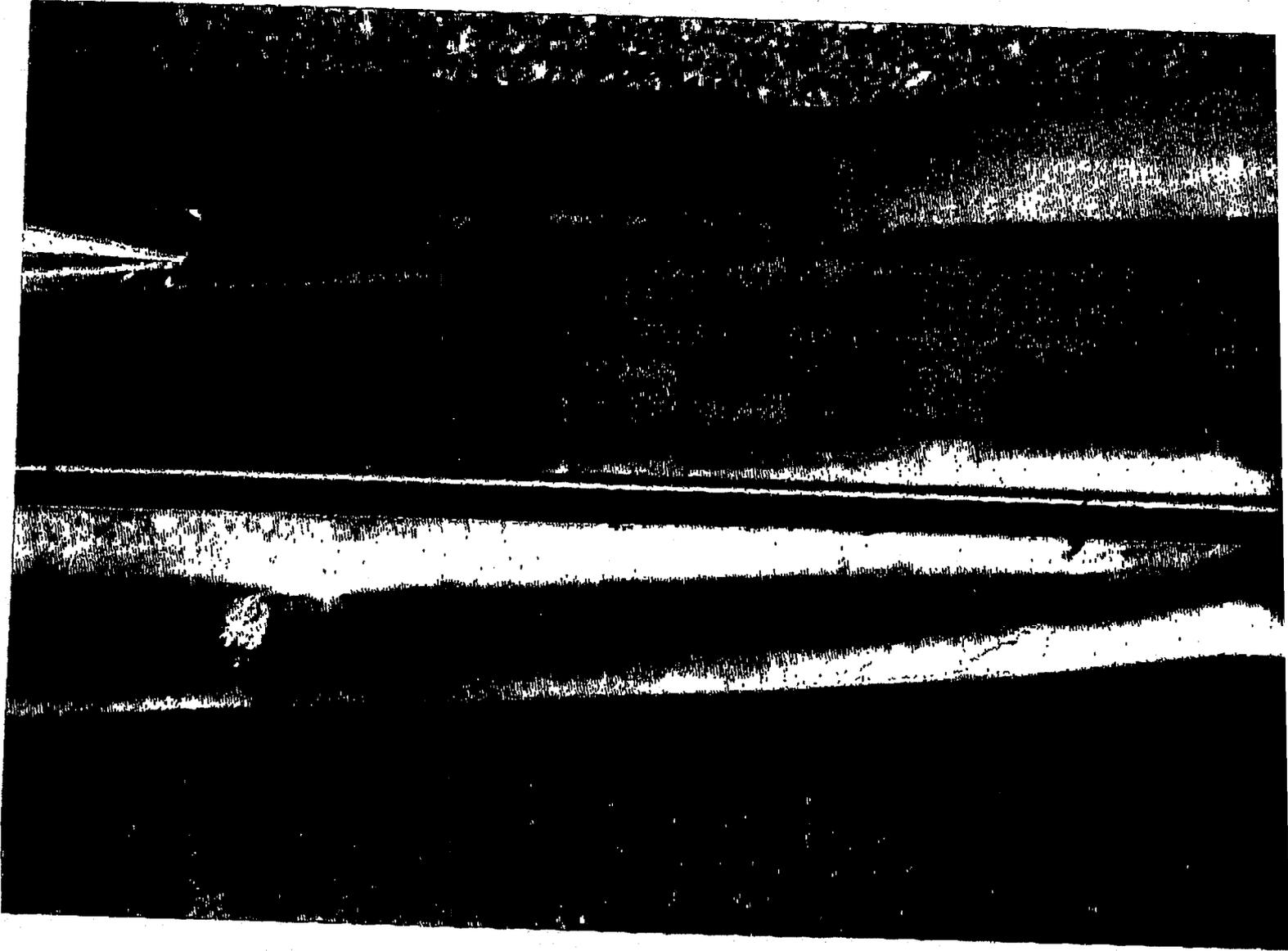
SNN Curved
Synovator Package.



MIT refurbished blade, shrink tube
degradation on the inner tube.

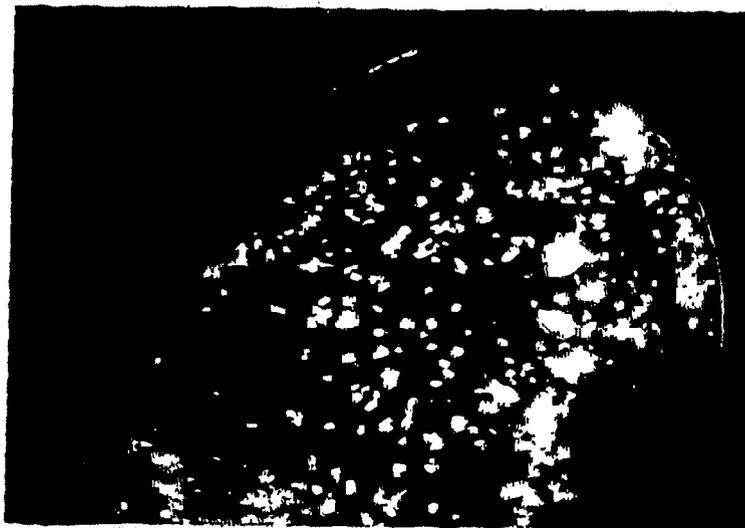








Inclisor, 4.5mm, inner blade lumen of new blade.



Refurbished TurboWhisker, 4.5mm, inner blade showing radial wear marks, loose particulate matter and deposits consistent with dried blood.



Refurbished TurboWhisker, 4.5mm inner blade lumen showing deposits consistent with dried blood.



Refurbished Incisor, 4.5mm inner blade lumen showing loose particulate matter and deposits consistent with dried blood.

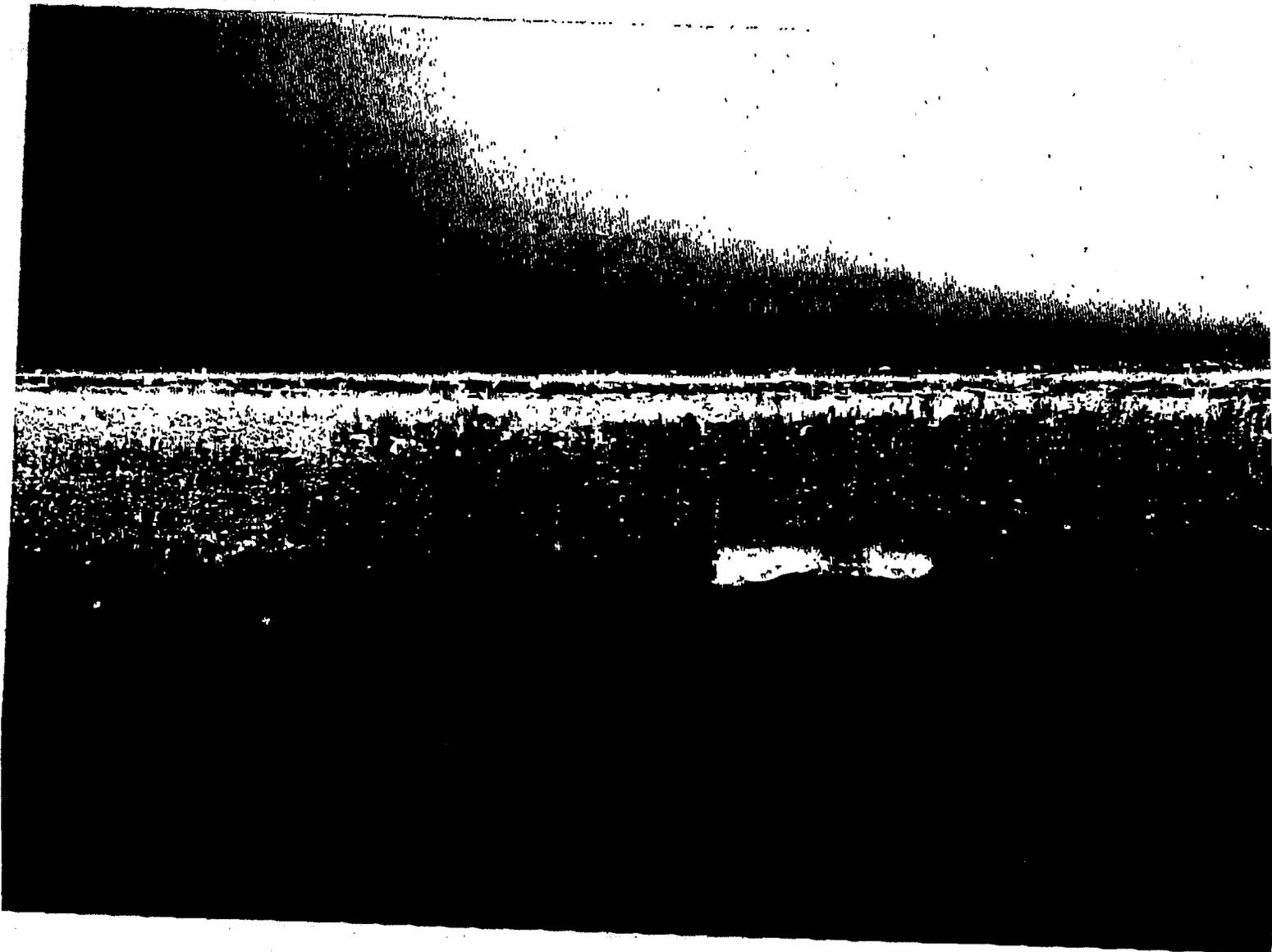


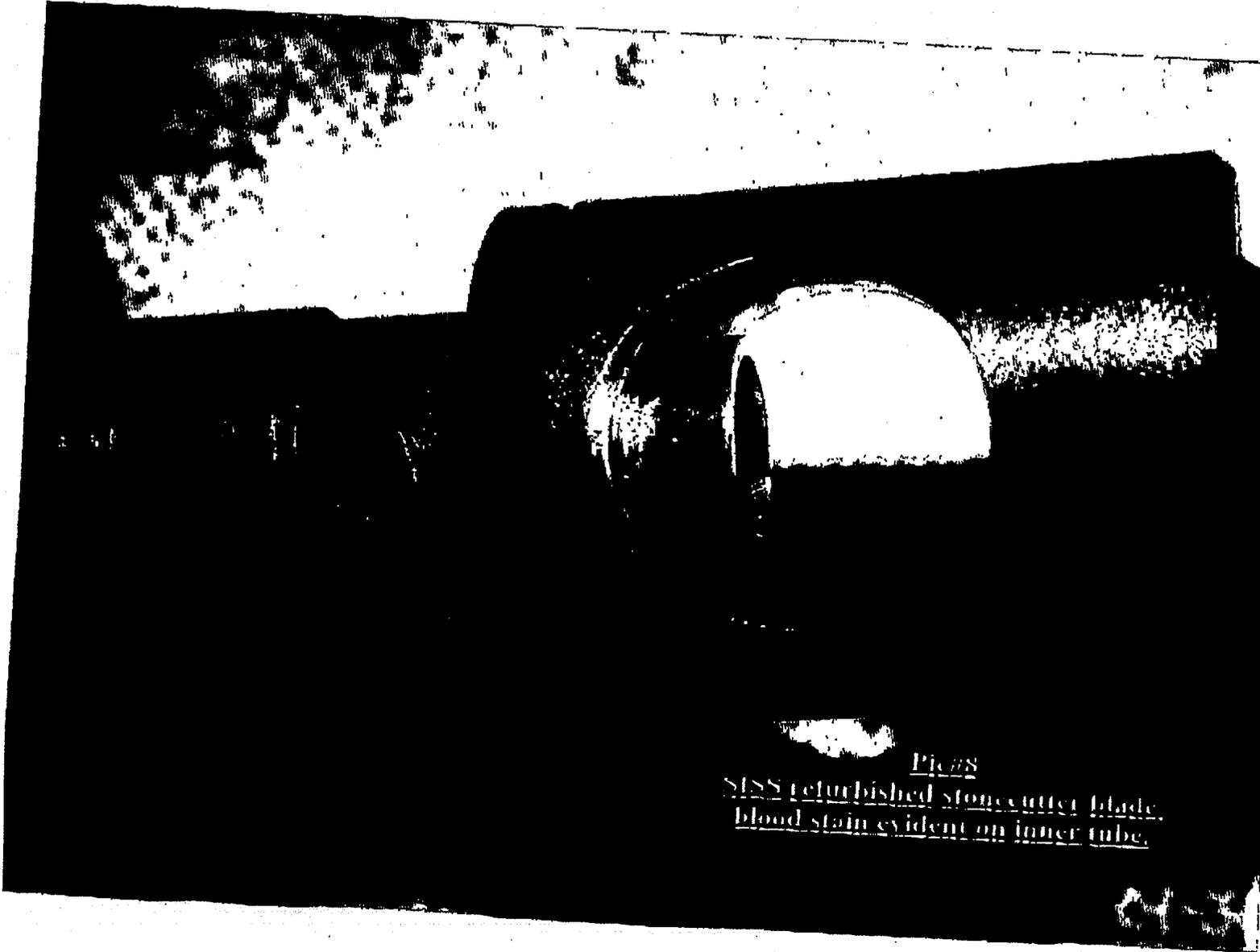
Refurbished TurboWhisker[®], 4.5mm, outer blade showing deposits consistent with dried blood.



Refurbished Cutter, 3.5mm, inner blade lumen showing loose particulates and deposits consistent with dried blood.







**MIT refurbished blade labeled as a Dyonics blade,
Dyonics mini blades have a "J" groove.**



MIT refurbished mini blade labeled as a
Dyonics blade.