



Flexible Endoscope Disposable Sheaths

PROVEN PROTECTION WITH A VIEW

Sterile and impervious to bacteria and viruses, these sheaths provide the ultimate in patient, staff and scope protection, without distortion.

- These flexible endoscope sheaths help reduce reprocessing and down time.
- Provides reduced chemical exposure for the endoscope, therefore resulting in lower service and repair costs.
- Less staff exposure to toxic disinfection chemicals.

BR46-15501

Flexible Rhinolaryngoscope Sheath, sterile, disposable,
for use with BR946-34260-300, 20 per box

UNIVERSAL
FIT



FEATURES

- Aseptic loading and disposal. Easy on, Easy off – No slip
- Validated barrier to micro organisms as small as 25nms
- Optically clear lens cover
- Latex-free
- Sterile, individually packaged, 20/box
- 5-year shelf life

Flexible Rhinolaryngoscope

BR Surgical is pleased to offer a premium-quality Flexible Rhinolaryngoscope designed for the needs of the physician in daily practice. High resolution and a specially designed multilens objective ensure the optimum picture quality you expect from a high-precision scope.

BR946-34260-300

Flexible Rhinolaryngoscope, Ø 3.4mm, 300mm



CALL FOR INFORMATION ABOUT BR SURGICAL'S FLEXIBLE SCOPE VIDEO SYSTEMS

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BR SURGICAL FLEXIBLE ENDOSCOPE DISPOSABLE SHEATH – INSTRUCTIONS FOR USE

PRECAUTIONS & WARNINGS

1. Prior to using the BR Surgical Disposable Endoscope Sheath, read these instructions completely. If you wish further in-service training, call BR Surgical at (888) 642-1366.
2. As with any sterile item, always inspect the integrity of the packaging for possible wetting or tearing and the enclosed product for damage prior to use.
3. Routinely inspect the insertion tube of the flexible endoscope for damage. In particular, check for dented or rolled over vinyl scope skin.
4. NEVER USE FORCE to insert or withdraw the sheath on or off your endoscope. This maneuver can damage the endoscope causing need for major repairs.
5. DO NOT ATTEMPT to re-sterilize or re-use the ONE TIME ONLY disposable product.

CAUTION: FAILURE TO FOLLOW INSTRUCTIONS CAREFULLY MAY CAUSE PATIENT INJURY.

OVERVIEW

The BR Surgical Disposable Endoscope Sheath is a **DISPOSABLE SINGLE USE ONLY** product, to encase a flexible endoscope's insertion tube and distal lens and to maintain a sterile barrier for patients undergoing endoscope procedures of the head and neck. It is also designed to provide a clear optical view via an optically clear lens cover. Its unique design supports aseptic and easy disposal of used endoscope covers.

To insure safe use of this endoscopic accessory, training is necessary. The clinician should be competent in the endoscopic procedure and the nursing staff knowledgeable in the proper care and handling of flexible endoscope being used.

Medical product disposal procedure must be followed in order to maintain patient and staff safety. Flexible endoscopes are delicate glass instruments and incorrect handling and reprocessing will cause damage.

SYSTEM DESCRIPTION

The BR Surgical Disposable Endoscope Sheath consists of a soft elastomer tube with endoscope insertion tube entry hub and distal optically clear lens cover. They contain no latex. The rigid protective tube in included to assist in loading the endoscope.

Packaged 20 sterile covers per box.

RECOMMENDED FLEX SCOPE CLEANING AND DISINFECTION PROTOCOLS

The BR Surgical Disposable Endoscope Sheath is FDA cleared as a Class II device used in conjunction with a nasopharyngoscope, a semi-critical device. If the scope cover was not torn during the endoscopy, please perform the below listed cleaning maneuvers and practice, at least, the minimum Intermediate Disinfection (ILD) Techniques.

CLEANING (after cover has been removed)

- Gently and thoroughly clean the entire scope with an appropriate instrument detergent. (Always follow your scope manufacturer's recommendations.)
- Rinse all surfaces completely with clean lukewarm water.
- Dry the scope thoroughly prior to disinfection.

DISINFECTION

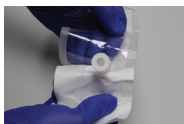
- Wipe the entire scope surface with a sponge soaked in 70% alcohol. Give close attention to gently wiping down the distal tip, as hard wiping could create a rollover at the rubber articulating section.
- Leak test prior to storing or reusing.
- Dry scope thoroughly prior to re-sheathing or storing.

INSERTION OF THE NASOPHARYNGOSCOPE INTO THE BR SURGICAL DISPOSABLE ENDOSCOPE SHEATH

Carefully read all instructions prior to sheathing the scope. The BR Surgical Disposable Endoscope Sheath is a ONE-TIME USE DISPOSABLE PRODUCT. Prior to opening the package, inspect the outer packaging for moisture damage or torn packaging. Please maintain sterile technique in loading these covers onto your endoscope.

NOTE: The sheath should glide onto the scope without resistance. If you experience any resistance, stop immediately and inspect the surface of the scope insertion tube for rolls, tears or dents. Forcing the insertion tube into the sheath may cause significant damage to the scope.

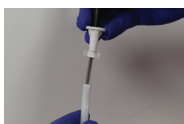
STEP 1: Open the teardown seal on the outer packaging until you have access to the insertion hub. **DO NOT** remove the sheath or its protective tube from the outer wrapper at this time.



STEP 2: Place the distal tip of the scope into the hub.



STEP 3: Grasping the hub, gently push the insertion tube into the cover. If you experience any counter pressure, **STOP** and inspect the insertion tube.



STEP 4: Remove the sheathed endoscope from the rigid protective tube. **NOTE:** The hub **WILL NOT** attach to the body of the endoscope.



STEP 5: The scope tip should seat within the lens cover. If not seated, gently pull the cover up the insertion until the scope's distal lens fits within the lens cover.

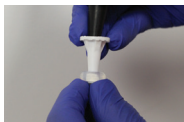
STEP 6: Roll down the locking ring onto the sheath to secure the cover into place.

NOTE: Keep the rigid cannula in the original packaging for use in proper disposal after the procedure. See the following section for information on proper disposal.

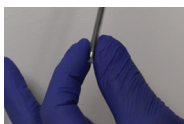
REMOVING COVER AND ASEPTICALLY DISPOSING OF A USED SHEATH

NOTE: Carefully read all instructions prior to removing the sheath from the scope. If you experience any resistance, stop immediately.

STEP 1: Roll up the locking ring onto the hub to release the sheath.



STEP 2: Grasp the distal tip (lens cover) of the scope sheath and slowly and gently remove it from the scope.



STEP 3: Place the used sheath into the protective tube and then into the original wrapper to dispose of per office, clinic, or hospital protocol.

STEP 4: The entire endoscope, including insertion tube, body and eyepiece must be washed and disinfected per manufacturer's instructions.

TROUBLESHOOTING DURING INSERTION

Situation	Recommended Action
While inserting tip, the scope will not easily slide into the white insertion hub of the sheath.	STOP! DO NOT PROCEED! 1. GENTLY withdraw the scope from the hub. If the scope will not easily withdraw, call BR Surgical at (888) 642-1366. 2. Closely inspect the endoscopes insertion tube, specifically the articulating tip section. 3. If upon examination, the scope insertion tube is found to be oversized, due to bunching, rolling or denting, DO NOT USE . The insertion tube section may have to be repaired.
Sheath inserts with nominal difficulty over the scope insertion tube, and no apparent articulation section roll over or bunching is observed.	1. Check to see that the distal scope insertion tube is straight and not angled at the articulation section. 2. The vinyl skin of the endoscope may have become tacky, creating drag. Clean the scope insertion tube with soap and water using scope manufacturer's recommendations. You may also apply a dusting of corn starch to the insertion tube only. Do not add lubrication into the lumen of the scope sheath.
Clinician visualizes glare through scope.	The distal lens tip of the endoscope may not be seated against the inside surface of the sheath's optically clear lens cover. Gently pull back the cover to seat the scope tip into the optically clear lens cover.

TROUBLESHOOTING DURING REMOVAL

Situation	Recommended Action
While removing the sheath you encounter some resistance.	STOP! PROCEED WITH CAUTION! Examine the sheath to make sure it has not rolled over and jammed itself onto the scope. To resolve this: 1. Grasp the sheath hub and distal tip and pull out the rolled over sheath. 2. GENTLY withdraw the scope from the hub. The sheath should now easily slide off. If you cannot resolve this, call BR Surgical at (888) 642-1366.