



[CUSTOMER]

N/REF:[CUSTOMER N°]/RNC3425

Date: 2013, September 6

URGENT – MEDICAL DEVICE RECALL
SBI rHead and uHead Sterile Packaged Stems

Small Bone Innovations is ordering the return of all rHead and uHead stem implants due to an increased risk of implants breaching the sterile pouches inside the shrink wrapped box. This return is mandatory for all items listed on page two.

The product is to be shipped immediately to SBI International at the address below using SBI Intl UPS account # **4E1V43**.

Products to be returned to SBI International, ZA Les Bruyères 019660 Péronnas - France
recall reference: [CUSTOMER N°]/RNC3425

Upon return of these products to SBI, the products will be credited to you, and will be re-packaged and re-sterilized immediately to be reallocated to the market as fast as possible.

Readily available implants will be returned to you, while implant banks for SBI's various rHead and uHead offerings will be also available through Customer Service as loaners until such time as sufficient levels of inventory have been repackaged. At that time, inventory will be fully re-deployed to the field.

Enclosed is a Product List document for you to complete, sign, and return with the products to SBI International. If product has been implanted there are no additional risks that have been identified other than those outlined in the package insert (Instructions for Use).

Thank you, in advance, for your cooperation.

Respectfully,

Florence LAUCK
Quality Manager

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URGENT – MEDICAL DEVICE RECALL – Sbi rHead and uHead Sterile Package Stems

Products to be returned

Type	Part#	Description
rHead	410-0100	rHead Standard Extended Stem,6mm Collar, Size1
	410-0101	rHead Standard Extended Stem,6mm Collar, Size2
	410-0102	rHead Standard Extended Stem, 6mm Collar, Size 3
	410-0103	rHead Standard Extended Stem, 6mm Collar, Size 4
	RHA-S1	# 1 radial stem implant (Sterile packed)
	RHA-S160	rHead, Radial Implant, 6mm Collar, Size 1
	RHA-S2	# 2 radial stem implant (Sterile packed)
	RHA-S260	rHead, Radial Implant, 6mm Collar, Size 2
	RHA-S3	# 3 radial stem implant (Sterile packed)
	RHA-S360	rHead, Radial Implant, 6mm Collar, Size 3
	RHA-S4	# 4 radial stem implant (Sterile packed)
	RHA-S460	rHead, Radial Implant, 6mm Collar, Size 4
rHead Recon Plasma Spray	310-2018	rHead Recon Stem Implant, Plasma Coated, Size 1
	310-2019	rHead Recon Stem Implant, Plasma Coated, Size 2
	310-2020	rHead Recon Stem Implant, Plasma Coated, Size 3
	310-2021	rHead Recon Stem Implant, Plasma Coated, Size 4
	310-2022	rHead Recon Stem Implant, 6mm Collar, Plasma Coated, Size 1
	310-2023	rHead Recon Stem Implant, 6mm Collar, Plasma Coated, Size 2
	310-2024	rHead Recon Stem Implant, 6mm Collar, Plasma Coated, Size 3
	310-2025	rHead Recon Stem Implant, 6mm Collar, Plasma Coated, Size 4
	RCN-S1	# 1 Bipolar stem implant (Sterile packed)
	RCN-S160	RHEAD RECON, STEM IMPLANT, NON-COATED, SIZE 1
	RCN-S2	# 2 Bipolar stem implant (Sterile packed)
	RCN-S260	RHEAD RECON, STEM IMPLANT, NON-COATED, SIZE 2
	RCN-S3	# 3 Bipolar stem implant (Sterile packed)
	RCN-S360	RHEAD RECON, STEM IMPLANT, NON-COATED, SIZE 3
	RCN-S4	# 4 Bipolar stem implant (Sterile packed)
	RCN-S460	RHEAD RECON, STEM IMPLANT, NON-COATED, SIZE 4
uHead	UHA-S1	# 1 Ulnar Stem Implant (Sterile packed)
	UHA-S120	# 1 Reconstruction Ulnar Stem Implant 20mm extension
	UHA-S2	# 2 Ulnar Stem Implant (Sterile packed)
	UHA-S220	# 2 Reconstruction Ulnar Stem Implant 20mm extension
	UHA-S3	# 3 Ulnar Stem Implant (Sterile packed)
	UHA-S320	# 3 Reconstruction Ulnar Stem Implant 20mm extension
	UHA-S4	# 4 Ulnar Stem Implant (Sterile packed)
	UHA-S420	# 4 Reconstruction Ulnar Stem Implant 20mm extension

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Part#	Expiry date#	Lot#	Qty delivered	Qty returned	Discrepancies	Reason for the discrepancies
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Signature and customer stamp: