



"CUSTOMER"

"COUNTRY"

N/REF: "CUSTOMER NUMBER"/RNC3647

Date: December 23, 2013

URGENT –MEDICAL DEVICE RECALL
SBI Remotion Radial Sterile Packaged

Small Bone Innovations is ordering the Remotion Radial 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 number.

Products to be returned to:

SBI International, ZA Les Bruyères, 01960 Péronnas - France

Recall reference: RNC3647

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 Remotion offering 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 and send with quantities, lots and expiry dates of implants to be returned.

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 Remotion Sterile Packaged Implants

Products to be returned

Type	Part#	Description
Remotion	WA/R-LL	Left, large distal radial component
	WA/R-LM	Left, medium distal radial component
	WA/R-LS	Left, small distal radial component
	WA/R-LXS	Left x-small distal radial component
	WA/R-RL	Right, large distal radial component
	WA/R-RM	Right, medium distal radial component
	WA/R-RS	Right, small distal radial component
	WA/R-RXS	Right x-small distal radial component