

To the ATTENTION of: Operating room manager

6 May 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
338.002	Guide Wire Ø 2.5 mm, with drill tip, length 300 mm, Cobalt-Chrome Alloy	4946169; 4947141; 4948369; 4955980; 4956958; 4957940; 4957941; 4962753; 4963803; 4963806; 4974650; 4975501; 4976184; 4976185; ;4983571 ;4984511; 6208949; 6218823; 6218824; 6283580; 6285734; 6302424; 6307581; 6351113; 6373826; 6383766; 6412852; 6414748; 6414749; 6422349; 6450340; 6481087; 6491335; 6491337; 6541070; 6541071; 6563593; 6563594; 6563595; 6566491; 6570213; 6588101; 6590131; 6600005; 6605837; 6606950; 6664779; 6669388; 6681686; 6681687; 6694103; 6694104; 6694105; 6694106; 6696664; 6696665; 6696666; 6696667; 6697797; 6704838; 6704840; 6710329; 6710330; 6710331; 6715520; 6715521; 6907877; 6927724; 6933620; 6956534; 6961574; 6964590; 6969810; 6976338; 6990050; 6995656; 7002135; 7006960; 7011466; 7017950; 7024444; 7033126; 7034317; 7040392; 7045178; 7052007; 7052008; 7056628; 7056629; 7062446; 7062447; 7072793; 7079732; 7086959; 7086960; 7099822; 7099823; 7105536; 7105537; 7114842; 7180077; 7198224; 7248253

Dear Sir/Madam

Synthes is initiating a medical device removal regarding the above mentioned lots of the Guide Wire Ø 2.5 mm, with drill tip, length 300 mm, Cobalt-Chrome Alloy. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

The wrong material (Stainless Steel) is indicated on the product label. The product is made of Cobalt Chrome (L605).

Patient risk:

The mislabelled product, if detected, may result in user dissatisfaction and use of an alternative product with no harm anticipated.

There is the unlikely potential that a user may desire to use a stainless steel guide wire because the patient has a known sensitivity to cobalt chrome-alloy. Although highly unlikely, if this situation were to occur the patient could experience an adverse tissue reaction.

Customer immediate actions:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.
2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

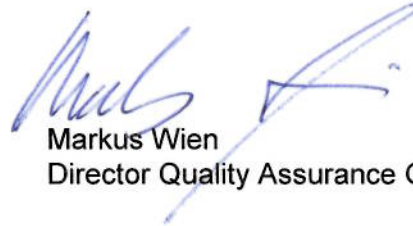
We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH



Claudia Allemann
Field Action Manager



Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

**Guide Wire Ø 2.5 mm, with drill tip, length 300 mm,
Cobalt-Chrome Alloy**

338.002

Verification Section

- We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.

- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____