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The Medical Products Agency's assessment of the plan for informational activities submitted by Nobel Biocare AB

Background

The Medical Products Agency (MPA) notified Nobel Biocare AB (company) in its decision of 6 December 2006 to

1. Clearly indicate possible causes for raised marginal bone resorption as well as describe how these can be avoided in instructions for use and educational programmes connected to the implants NobelDirect and NobelPerfect;
2. Clearly indicate the user qualifications and skills required to be able to use the implants safely in the instructions for use and marketing materials;
3. Inform customers and authorities for medical devices in the countries concerned in an Advisory Note of the measures listed above and the background;
4. Submit the revised instructions for use when completed to customers and the authorities mentioned above;
5. Submit a plan including a time plan for the above measures to the MPA no later than 8 January 2007;
6. Refrain from sales-promotion activities for the NobelDirect and NobelPerfect implants until the measures in the plan have been carried out.

The company submitted a suggested plan of action and time plan on 5 January 2007. In a written communication on 15 February 2007, the MPA requested supplementary information, primarily concerning points 1 and 2. The supplementary information from Nobel Biocare was received on 12 March 2007. The MPA's commissioned external expert group has declared its opinion about the company's suggested plan of action and time plan including additional information supplied by the company. The National Board of Health and Welfare responded to the request from the MPA to give its opinion on the desired level of operator competence that perform dental implants. The company has been advised of the opinions of both the expert group and the National Board of

Health and Welfare and in the former case, has submitted comments concerning the opinions.

In addition to the above activities, the MPA has also reviewed the instructions for use/folders with the following articles numbers, all connected to the implant NobelDirect: 9643, 15097, 15423, 15575, 15662, 15737 and 16161.

After a review of the above named materials, the MPA makes the following assessment concerning the measures that the company envisages to take with reference to the first two points in the decision of 6 December 2006.

About the reasons for the raised marginal bone resorption and measures to avoid these

Regarding possible reasons for the raised marginal bone resorption, the company gives four steps in the treatment that are of particular importance. The company plans to include a special page in the beginning of the manuals with directions on how these shall be handled. The steps that are highlighted as especially important are:

- The vertical placement of the implants,
- The torque when tightening the implants,
- Preparation of the implants, and
- Making a temporary replacement.

In reference to the vertical placement of the implants, special emphasis is given to avoid inserting the implants too deeply. How deep is too deep is not indicated. The operator is encouraged to follow the instructions later on in the manual. Nor in this later description is there any indication of how deep is too deep. Instead, a warning has been added indicating that placing the implant too deeply may result in an accentuated remodelling of the bone.

The supplementary information supplied by the company, however, states that the aimed vertical placement of the implant should be to place it so the first thread gets in level with the alveolar crest. This information is not indicated in the action plan or in the above named instructions for use/folders. In fact, 5575 indicates that... "Because the TiUnite surface goes beyond the implant threads and onto the collar of the NobelDirect implant, it is possible to vary the vertical placement"... which can be perceived to mean that placement with the first thread under the bone crest will not influence remodelling. The risk for such an interpretation is strengthened in 15097 (p. 10) and 15662 (p.7) where illustrations show the implant with the first thread clearly under the alveolar crest.

When using the flapless technique for implantation, the operator cannot see the level of the bone. How the desired vertical placement can be ensured in this situation is presently not indicated in 15423 or 15662. To clarify this in the manuals, Nobel Biocare intends to add marks to existing illustrations outlined to indicate the thickness of the soft tissues with a fixed measure of 2 mm. There is no clarifying text. As a considerably clearer alternative appears the instructions currently in use in 9643 (p. 18), which states... "Measure the thickness of the tissue with a probe. Drill ...to the appropriate

depth (the thickness of the tissue included” or in 15097 (p. 13): “Flapless procedure – Measure tissue thickness with probe. Add tissue thickness to drilling depth for correct site preparation.”

The MPA is of the opinion that the instructions for use/folders in reference to the NobelDirect and NobelPerfect implants shall clearly indicate that the implants shall be placed so the first thread comes in level with the alveolar bone crest. Measures to ensure this with the flapless technique shall be clearly described.

Preparation of the NobelDirect implant must take place *in situ*. This poses a danger for the surrounding bone tissue to be exposed to harmful heat generation. The directions indicate abundant cooling irrigation. The preparation of the abutment portion shall also be limited to a minimum, especially when it is performed in connection with the implantation. The upper limit for “minimum” is not specified.

An example of the way the upper limit can be worded is in 9643 (p.7) and 15662 (p.5). There it indicates that the need for angulation by grinding of the abutment part should not exceed certain degrees, in this case to avoid inappropriate loading forces. A corresponding recommendation with reference to the danger for harmful heat generation is lacking. The content of the recommendation should be that if a need for preparation to a certain extent is foreseen, another (two-part) implant system should be chosen.

The MPA accepts the company’s suggested additional instructions to avoid the other two listed reasons for raised marginal bone resorption (tightening of the implant and the make of a temporary replacement).

About the qualifications and skills required when using the implants

In regards to the qualifications and skills required to be able to use the implants safely, Nobel Biocare emphasizes that the company cannot demand more than dentist certification. However, the company intends to create a web-based self-test for participants in the company’s educational programmes. The National Board of Health and Welfare suggests that these programmes be preceded by a diagnostic test to ensure that the level of the courses is at the right level.

However, this does not solve the question of how to build up the practical skills. The National Board of Health and Welfare states in their opinion that the first cases shall be carried out together with an experienced operator and indicated, if not as a legal point, by a clear manufacturer’s statement. Nobel Biocare has declared that they have the same opinion but this is not stated in any of the instructions for use/folders reviewed by the MPA. Since implant treatment requires great skilfulness and in addition in this case, concerns products and methods that are relatively new, it appears inappropriate to begin the description with the words “you don’t have to be a specialist to prepare the site for NobelDirect” in 15585.

The MPA is of the opinion that it shall be clearly stated in the instructions for use/folders and in educational materials that the first implants shall be carried out together with an experienced operator.

Generally concerning the directions for use

About the question of how to ensure safe use of the implants, the MPA in addition wants to point out the concentrated, but nevertheless detailed compilation of warning texts and cautionary measures given in the general instructions for use 15737. This information is not repeated in the other six instructions for use/folders. There are no cross-references to the general instructions for use 15737.

The MPA points out that the warnings and cautionary measures found in the general instructions for use 15737 shall also be repeated in an appropriate way in the other instructions for use/folders that refer to NobelDirect and NobelPerfect.

Summary of the MPA's assessment and requirements

The MPA is of the opinion that in the company's instructions for use/folders referring to NobelDirect and NobelPerfect implants, the company shall

- clearly state that the implants shall be placed so the first thread is positioned in level with the alveolar bone crest;
- clearly and thoroughly describe the measures to take to ensure that this can be done with the flapless technique;
- indicate when the preparation of the spacer part can be seen to require a certain extent, the two-part implant system should be chosen;
- clearly state that the first implants shall be carried out together with an experienced operator; and,
- repeat the warnings and cautionary measures texts that are found in the general instructions for use 15737 in an appropriate way.

To the extent that the above are applicable to directions belonging to the other implant systems in the company's portfolio, these should be modified so that the consensus is maintained throughout.

The MPA expects to receive the plan for how Nobel Biocare will formulate the measures to meet the requirements above to infer in the instructions for use/folders connected to the products NobelDirect and NobelPerfect implants no later than 20 August 2007.

On behalf of the Medical Products Agency,

Lennart Philipson
Director